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DEPARTMENT OF MEDICINE
CALIFORNIA COLLEGE OF MEDICINE

Please reply to:

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Harmon McAllister, Ph.D.
Council for Tobacco Research
900 3rd Avenue
New York, NY 10022

March 1, 1991

Dear Dr.Mc Allister

I am sending this letter as a *Letter of Intent* for the proposal of a research study. I had requested an application form and instructions for this letter, but have not received them. Since I will be on vacation next week and there is a deadline for submission of *Letter of Intent*, I am sending this letter today.

The proposed research will involve an examination of the bronchial cytology of smoking patients, a determination of patients showing metaplasia of bronchial cells, therapy of such patients with pharmacologic doses of folic acid and vitamin B_{12}, followup cytology during a six-month period of therapy and repeat cytology at the end of twelve months. Chest xrays will be taken prior to therapy, at the end of one year and at the end of two and three years. This study will be conducted by my staff at the VA Medical Center and by a research group at the University of Oregon, Health Science Center. We plan to enlist 100-150 patients randomly selected from a much larger group of smoking patients. A control group with metaplasia and no therapy will be used for comparison during the same time intervals.

There is one report in the literature showing benefit with this regimen on a smaller sample and we have also demonstrated apparent benefit in a pilot study.

Patients will be excluded if any chest xray abnormalities are already present, the patient has other risk factors for malignancy including occupational risk, positive family history, or prior malignancy. Patients with immunologic deficiency will also be excluded.

In addition to chest xray and sputum cytology, each patient will have a blood count, SMA-20, and urinalysis prior to and during the course of therapy. B_{12} and folic acid levels will also be determined and patients with folate or B_{12} deficiency prior to inclusion into the study will be excluded.

This study would appear to have great potential for reversing or modifying metaplasia and possibly decreasing the incidence of lung cancer. The formal application form, together with a budget, will be submitted as soon as I receive the application forms and instructions.

Sincerely,

Eugene Coodley

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